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10/037,757	10/18/2001	Carol T. Schembri	10004108-1	7503

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AGILENT TECHNOLOGIES, INC.
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EXAMINER

FORMAN, BETTY J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,757

Applicant(s)

SCHEMBRI ET AL.

Examiner

BJ Forman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1-24 in papers filed 27 February is acknowledged. The traversal is on the grounds that it would not be undue burden to examine the claims of all groups I and II. However, it is maintained that undue burden would be required to examine the claims of group II along with claims of group I as evidenced by the fact that the claims of groups I and II have acquired a separate status in the art as recognized by their different classifications as recognized by their divergent subject matter and because a search of the subject matter of invention I is not co-extensive with a search of invention II. Specifically, a search of the subject matter of Invention I would encompass array components including substrate materials (e.g. plastics, glasses, metals) and substrate characteristics (e.g. absorbance). In contrast, a search of the subject matter of Invention II would encompass methods of reading assays including multiple assays steps (e.g. illuminations and detection). As such, a search of Invention I would not be co-extensive with that of Invention II.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because of the following informalities:
- a. Page 10 of the specification recites a nucleic acid sequence that is not identified by a SEQ ID NO: as required under 37 C.F.R. 1.821(d).
 - b. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed e.g. Polymer Array Assembly.

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Appropriate correction is required.

Claim Rejections - 35 USC § 112

First paragraph of 35 U.S.C. 112: Enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a plastic base layer having a fluorescence of at least 10 reference units. While the specification is enabling for the an array assembly having a plastic base layer, claimed reference units are not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirements and whether undue experimentation would be required to make and use the claimed invention (see *In re Wands*, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404, 1988). These factors include but are not limited to:

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Nature of the Invention

The claims are drawn to an array assembly comprising a plastic base layer having a fluorescence of at least 10 reference units. The nature of the invention is such that units of fluorescent measurement requires some unit standard or standard of measurement.

The specification at page 9, lines 11-20 describes "reference unit":

"Reference unit" in relation to fluorescence measurements herein means the maximum fluorescence obtainable from a fused silica, or one-third the maximum value obtainable from a borosilicate glass. All fluorescence measurements herein, unless otherwise indicated, are integrated fluorescence emission energies from 547 nm to 597 nm, which result from a 1 mm thick section of material, using a monochromated high pressure Xe lamp excitation source centered at 532 nm with a width at half-maximum of about 5 nm. All ratios assume the same unit area of illuminated material. The following may be used as the foregoing referenced materials (available from the National Institute of Standards and Technology, Maryland, U.S.A.): fused silica - Standard Sample 198; borosilicate glass-Standard Reference Material 93a.

The above description does not describe numerous elements required to define "reference unit" in such a way as to enable one of skill in the art to make and use the claimed invention. The missing elements include the type of Xe lamp used in the measurement. The type of lamp would be essential because the lamps differ by voltage and/or power and differences in voltage and/or power result in different emission energies and hence different fluorescent measurements. A second missing element is the geometry of illumination. The geometry includes, angle of illumination, the light path relative to the surface, and the position of the fluorescent detector relative to the surface. All of these influence the amount of fluorescence measured from the glass. Furthermore, it is unclear whether the reference unit is a single value or a variable based on environmental conditions. The nature of the invention is such that units of measurement requires some unit standard or standard of measurement. However, the specification has not described the units so as to enable one of skill in the art to make and use the claimed invention.

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State of the Prior Art

The claims are drawn to an array assembly comprising a plastic base layer having a fluorescence of at least 10 reference units. The state of the prior art is such that the claimed reference units are not taught or described in the prior art. Therefore, the reference units are not a known standard of measurement. Because the prior art and instant specification do not or describe the claimed reference units, the claimed invention is not enabled.

Level of Predictability in the Art

The claims are drawn to an array assembly comprising a plastic base layer having a fluorescence of at least 10 reference units. The specification describes "reference unit" at page 9, lines 11-20 as reiterated above. Numerous elements influence fluorescence measurements as discussed above. However, the specification does not teach or describe these elements. Absent a description of elements including type of Xe lamp, geometry of illumination and environmental conditions of illumination, the level of predictability in the art for determining a reference unit as a standard of measurement would be very low.

Existence of Working Examples

The specification does not teach working examples of the claimed reference units.

Quantity of Experimentation Required

The claims are drawn to an array assembly comprising a plastic base layer having a fluorescence of at least 10 reference units. In view of the nature of the invention in which units of fluorescent measurement requires some unit standard or standard of measurement; in view of the state of the prior art which does not teach or describe the claimed reference unit; in view of the of unpredictability in the art with regard to providing a reference unit of fluorescence measurement; and in view of the lack of working examples of the claimed invention, it would require undue experimentation for one skilled in the art to make and use the invention as claimed.

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Second paragraph of 35 U.S.C. 112: Indefinite

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is indefinite for the recitation "using a plastic base layer..." because it is unclear whether the recitation is a method step of using and if so, how the layer is used.

Claim 19 is indefinite because the claim is drawn to the array assembly of Claim 15. However, Claim 15 is drawn to a method of fabricating. Therefore, it is unclear how or whether the recitation of Claim 19 limits the method steps of Claim 15.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application

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filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 14, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Rava et al (U.S. Patent No. 5,545,531, issued 13 August 1996) as defined by Academic Press Dictionary of Science and Technology, Morris, C.G. ed. Academic Press, Inc. San Diego, 1992, page 1667).

Regarding Claim 1, Rava et al disclose an array assembly comprising a plastic base layer (i.e. microtiter plate) a glass layer forward of the base plate i.e. glass substrate within the well and above the bottom inner surface of the plastic well (Column 8, lines 22-28 and Column 9, lines 36-38), and an array of polymers having a pattern of features on a front (upper) surface of the glass (Column 4, lines 1-3 and Column 7, lines 60-65).

Rava et al teach their microtiter plate comprises various known polymers e.g. "a variety of polymers already used for microtiter plates including, for example, (poly)tetrafluoroethylene, (poly)vinylidenedifluoride, polypropylene, polystyrene, polycarbonate, or combinations thereof (Column 8, lines 50-60). The Academic Press Dictionary of Science and Technology defines "plastic" as "any of a various synthetic or organic material that can be molded or shaped....for example, polymers". Rava et al teach the microtiter plates are composed of polymers (Column 8, lines 50-60). As such, they teach the plastic base layer as claimed.

The claim is drawn to a glass plate "forward" of the base layer and features on a "front" surface. The "forward" position of the glass plate is interpreted to encompass any positional relationship between the glass plate and base layer because the "forward" position would be relative to the positioning of the array assembly within space and/or a person observing the array assembly. For example, a glass positioned under a plastic layer would be forward of the plastic layer upon rotation of the glass and plastic. Furthermore, the claim does not require any assembly or physical contact between the glass plate and base layer but merely that the

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plate be forward of the base. As such, the claim encompasses any combination of glass substrate plastic base.

Regarding Claim 2, Rava et al disclose the array wherein the polymers are biopolymers (Column 3, lines 39-48).

Regarding Claim 14, Rava et al disclose a method of fabricating an array comprising a plastic base layer (i.e. microtiter plate) a glass layer forward of the base plate i.e. glass substrate within the well and above the bottom inner surface of the plastic well (Column 8, lines 22-28 and Column 9, lines 36-38), and forming an array of polymers having a pattern of features on a front (upper) surface of the glass (Column 4, lines 1-3 and Column 7, lines 60-65).

Regarding Claim 23, Rava et al disclose the method wherein multiple arrays are formed by depositing drops onto the front surface of the glass containing polymers or polymer precursors (column 9, line 53-Column 10, line 44).

Regarding Claim 24, Rava et al disclose the method wherein the polymers are polynucleotides or peptides (Column 3, lines 39-48).

9. Claims 1-5, 9-16, 20-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al (U.S. Patent Application Publication No. 2001/0051714, filed 10 January 2001).

Regarding Claim 1, Chen et al disclose an array assembly comprising a plastic base layer a glass layer forward of the base plate (§ 66), and an array of polymers having a pattern of features on a front (upper) surface of the glass (§ 57).

Regarding Claim 2, Chen et al disclose the array wherein the polymers are biopolymers (§ 58).

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Regarding Claim 3, Chen et al disclose the array assembly further comprising an opaque (metallic) layer between the base and glass layers (¶ 66, lines 9-15).

Regarding Claim 4, Chen et al disclose the array assembly further comprising a reflective (metallic) layer between the base and glass layers (¶ 66, lines 9-15).

Regarding Claim 5, Chen et al disclose the array wherein the reflective layer comprises a metal (¶ 66, lines 9-15).

Regarding Claim 9, the claimed assembly is defined as having a base layer that absorbs at least 10% of light at 532 nm. The recitation describes functional aspects of the layer but does not describe structural components. Because the claim does not further limit the structures of Claim 4 and because Chen discloses the structural limitations recited in Claim 4, Chen also disclose the assembly as claimed.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114).

Regarding Claim 10, Chen et al disclose the assembly further comprising an identifier on the back of the base layer (¶ 118).

Regarding Claim 11, Chen et al disclose the assembly is flexible (¶ 66-67).

Regarding Claim 12, Chen et al disclose the assembly is in the form of an elongated web i.e. elongated (e.g. ¶ 77). It is noted that the claim requires the assembly to "in the form of an elongated web". The claim does not require the assembly be a web, but merely in the form of an elongated web. Chen teach their assembly is elongated (e.g. Fig. 1, 3, 4).

Regarding Claim 13, Chen et al disclose the assembly comprising multiple arrays along the front surface (¶ 57, lines 1-6).

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Regarding Claim 14, Chen et al disclose a method of fabricating an array assembly using a with a glass layer bound thereto (¶ 66) and forming an array of polymers having a pattern of features on a front (upper) surface of the glass (¶ 57, lines 1-6).

Regarding Claim 15, Chen et al disclose the method wherein there is a reflective (metallic) layer between the base and glass layers (¶ 66, lines 9-15).

Regarding Claim 16, Chen et al disclose the method wherein the reflective layer comprises a metal (¶ 66, lines 9-15).

Regarding Claim 20, Chen et al disclose the assembly further comprising an identifier on the back of the base layer (¶ 118).

Regarding Claim 21, Chen et al disclose the method wherein assembly is flexible (¶ 66-67).

Regarding Claim 22, Chen et al disclose the method wherein assembly is in the form of an elongated web i.e. elongated (e.g. ¶ 77). It is noted that the claim requires the assembly to "in the form of an elongated web". The claim does not require the assembly be a web, but merely in the form of an elongated web. Chen teach their assembly is elongated (e.g. Fig. 1, 3, 4).

Regarding Claim 23, Chen et al disclose the method wherein multiple arrays are formed by depositing drops onto the front surface of the glass layer wherein the drops contain polymers or polymer precursors (e.g. Fig. 3 and ¶ 80, 97 and 117).

Regarding Claim 24, Chen et al disclose the method wherein the polymers are polynucleotides or peptides (¶ 80).

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10. Claims 6 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al (U.S. Patent Application Publication No. 2001/0051714, filed 10 January 2001) as defined by Academic Press Dictionary of Science and Technology, Morris, C.G. ed. Academic Press, Inc. San Diego, 1992, page 634).

Regarding Claim 6 and 17, Chen et al disclose the assembly comprising multiple layers i.e. glass and plastic (§ 66). Academic Press Dictionary of Science and Technology cites glass and plastic as examples of dielectric materials. Hence, Chen et al disclose the assembly comprising multiple layers of dielectric material as claimed.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (U.S. Patent Application Publication No. 2001/0051714, filed 10 January 2001).

Regarding Claims 7 and 18, Chen et al disclose an array assembly and method of making the assembly comprising a plastic base layer a glass layer forward of the base plate (§ 66), and an array of polymers having a pattern of features on a front (upper) surface of the

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glass (§ 57) wherein the substrate has a thickness (diameter) of 125µ m and teaches that other diameters are available (§ 68) but they do not specifically teach a thickness of 40 to 200nm.

However, the courts have stated that "where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device." *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). Therefore, the claimed thickness does not distinguish the instant invention over the glass layer of Chen et al because one of ordinary skill in the art would have expected the glass layers to perform equally. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the glass thickness of Chen et al based on their suggestion to do so (§ 68) for the obvious benefits of optimizing the thickness to thereby optimize results.

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/285,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an array assembly and methods of making same. The claims differ only in the arrangement of the limitations within the claim sets. For example, instant claim 1 is drawn to an array assembly comprising a base layer and glass layer and dependent claim 4-5 limit the assembly to further comprising a reflective/metal layer and dependent claim 11 limits the assembly to flexible. Claim 1 of the '759 application includes the reflective and flexible limitations. The claims further differ in that Claims 3, 10, 11, 17 are drawn to species of plastic and glass while independent Claim 1 of the instant application is drawn to the genus of plastic and glass.

The courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

Because the courts have stated that a genus is obvious in view of a species and because the claim sets differ only in the arrangement of the limitations, the instantly claimed invention would have been obvious view of the invention of claims in the '759 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
May 6, 2004